EXHIBIT A

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, WA

Appeal of:	**VEIN AND WELLNESS GROUP LLC**	OMHA Appeal No.:	**3-5707304310**
Beneficiary:	**A. RINEHART**	Medicare Part:	B
Medicare No.:	*******4751A**	Before:	**Andrea Barraclough** Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, a **FAVORABLE** decision issues for the physician's surgical services (billed under code 37241) that Appellant provided to A. Rinehart (beneficiary) on July 31, 2014 (date of service). Medicare shall cover and pay for the services at issue.

PROCEDURAL HISTORY

A. Case Events

Appellant sought reimbursement for surgical services under code 37241. File 4, pgs. 40-43. The claim was paid on initial determination. On November 18, 2016, the Review Audit Contractor (RAC) determined an overpayment had been issued. File 4, pgs. 20-22. On December 27, 2016, the Medicare Administrative Contractor (MAC) denied the claims at issue on redetermination, agreeing with the RAC finding of an overpayment. File 4, pgs. 40-43. On February 2, 2017, the Qualified Independent Contactor (QIC) denied the claims on reconsideration. File 2, pgs. 1-4.

On February 22, 2017, the Office of Medicare Hearings and Appeals (OMHA) received Appellant's timely request for a hearing by an Administrative Law Judge (ALJ), which met all jurisdictional requirements. File 1, pg. 2.

Pursuant to proper notice, Appellant's hearing was conducted by telephone on January 6, 2021. File 12. Attorney Debra Parrish appeared as counsel for Appellant. Appellant Dr. Kelly O'Donnell also appeared and testified. *Id.* No other parties appeared for the hearing. *Id.* Files 1-8 were admitted as exhibits without objection. *Id.*

In its request for hearing, Appellant did not indicate that it had new evidence to present; however, Appellant's request for hearing included medical evidence not previously part of the

redetermination file. *See* File 1, pg. 2; File 4. At the hearing, counsel for Appellant indicated that the records that were seemingly new before this ALJ had in fact been part of the medical records at earlier levels of appeal; she opined they had not been transmitted properly from the levels below. *See* File 12. This ALJ notes that the copy of the redetermination record before me contains numerous blank pages, which appear to be caused by a copying or faxing error; this supports the possibility that the medical evidence included with the ALJ request form is likely not new. For this reason, the medical records appearing along with the ALJ request form will be admitted for good cause under 42 C.F.R. § 405.1028(a)(2)(iv).

Further, during the course of the hearing, it became evident that additional records that Appellant thought were already admitted but which were not included with the Request for an ALJ hearing were also going to be needed. Thus, following the hearing, the record was kept open until January 22, 2021, at 5:00 pm, Pacific Standard Time, for the additional medical evidence to be procured and submitted. At the hearing, Exhibits (Files) 1-9 were admitted without objection. After the hearing, Exhibits (Files) 10-12 were administratively admitted, with the pre-hearing brief entered as Exhibit (File) 10, the additional medical records entered as Exhibit (File) 11, and the Hearing Audio entered as Exhibit (File) 12.[1] Later, Exhibits 11 and 13 were omitted where it was revealed they contained records germane to another patient. The relevant records only as to the instant beneficiary were reinserted as Exhibit 14. Thus, this ALJ enters and considers Exhibits (Files) 1 through 14 (excluding duplicates and omissions) in rendering this decision.

ISSUES

1. Were the physician's surgical services properly billed under code 37214 such that they were covered and payable on the date of service?

2. If the services are not covered, do the limitation of liability provisions under Section 1879 of the Act or any other law apply? If not, who is financially responsible?

APPLICABLE LAW AND POLICY

I. Scope and Standard of Review

A. Scope of Review

The issues before the ALJ include all issues established in the initial, redetermined, or reconsidered claims and appeals that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a). The ALJ may decide a case on the record and not conduct a hearing if the Appellant and all other parties indicate in writing that they do not wish to appear before the ALJ. 42 C.F.R. § 405.1038. Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42

[1] The additional medical records were entered in duplicate as Exhibit 13 as well; however, because they are duplicated, they are not considered.

C.F.R. § 405.1046(a). The decision will be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

B. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the entirety of the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. *De novo* review requires the ALJ to review and evaluate all of the evidence without regard to the findings or prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

The burden of proving each element of a Medicare claim lies with the Appellant, who must prove their case by a preponderance of the evidence. *See* Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030.

II. Applicable Law (Medicare Sections/ Regulations/Other Authority)

A. Authority

All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII and XIX of the Act, and all implementing Codes of Federal Regulations (CFRs) are binding on ALJs. 42 C.F.R. § 405.1063. National Coverage Determination (NCD) guidelines are also binding precedent for ALJs and are the only source of regulation that establishes or changes substantive legal standards governing the scope of Medicare benefits or payments. 42 C.F.R. § 405.1060.

The Centers for Medicare and Medicaid Services (CMS) and its contractors can and do issue non-binding policy guidance describing criteria for coverage of selected types of medical items and services in the form of manuals (CMS Manuals), local medical review policies (LMRPs), and Local Coverage Determinations (LCDs). ALJs will give substantial deference to LCDs, LMRPs, or CMS Manuals when applicable, and if they do not follow these policies, they must explain why in their decision. *See* 42 C.F.R. § 405.1062.

Prior decisions of the Medicare Appeals Council (the Council), which is the Level 4 appeals level for Medicare claims governed by the Departmental Appeals Board, are not binding unless the Chair of the Departmental Appeals Board deems them precedential. 42 C.F.R. § 405.1063. In all other cases, a decision of the Council may act as persuasive guidance from which the ALJ may depart at their discretion.

B. Medicare Generally

Sections 1831 and 1832 of the Act, and 42 C.F.R. § 410, establish the Supplemental Medical Insurance Program for the aged and disabled under Part B and outline Part B benefits

and entitlements. Under § 1832(a)(2)(B) of the Act, Medicare will make direct payment to a medical or other health services provider or contractor that has provided medical services or equipment to a beneficiary. However, Medicare will not make payment unless sufficient information exists determining that the amount is proper and should be paid. 42 U.S.C. § 1395l, 42 C.F.R. § 424.5(6).

It is the responsibility of an Appellant to furnish sufficient information and documentation to support its claims for a Medicare payment. 42 C.F.R. § 424.5(a)(6). No adjudicator is under an obligation to seek additional documentation or supplement the record.

Section 1870 of the Act provides the authority for waiver of overpayments and other payment adjustments for incorrect payments on behalf of individuals. Overpayments shall not be recovered with respect to an individual who is "without fault." 42 U.S.C. § 1395gg.

C. Law Related to Condition and Service at Issue

1. Binding Authority - *Part B and Outpatient Services*

The Supplementary Medical Insurance program (Part B of Title XVIII of the Social Security Act) provides coverage for (1) a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, (2) for outpatient hospital services, and (3) for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. The term "physicians' services" is defined in Section 1861(q) of the Act as professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)[an intern or a resident-in-training]).

Importantly, as discusses below, on the date of service, there was no LCD on point to the actual procedure being performed.

FINDINGS OF FACT AND ANALYSIS

After careful consideration of the entire record, a preponderance of the evidence establishes the following:

A. Factual Findings

Hearing Statements

1. At the hearing, Ms. Parrish argued that this case regards a Mechanical Occlusion Chemically Assisted Ablation (MOCA) varicose vein treatment and whether CPT code 37241 was the appropriate code for the doctor to bill for that procedure on the date of service. File 12, 15:17-22:04. She noted that the MOCA procedure was relatively new and did not yet have its own CPT code in 2014 and 2015. *Id.* Dr. O'Donnell (the provider at Appellant organization) had

been told by the manufacturer of the surgical implements related to MOCA to use code 37241 in the absence of a specifically applicable code. *Id.* The actual on-point codes for MOCA (which are 364772 and 36473) did not come out until 2017. *Id.* The application process for getting a specific code generated for the MOCA procedure began in 2016. *Id.* Just after applying for the new CPT code for MOCA, Novitas started visiting users of the MOCA procedure to tell them not to use code 37241 anymore and to use the general surgery code 37999 in the interim until the MOCA-specific codes were approved. *Id.* Once Novitas told Dr. O'Donnell not to use 37241 and instead use the general surgery code, Dr. O'Donnell did so. *Id.* But, this interaction with Novitas happened in 2016, after the date of service here. *Id.* Ms. Parrish argued that the most appropriate code on the date of service at issue was 37241 as it was closest to the actual procedure; thus, it was appropriate for Dr. O'Donnell to use this code. File 12, 15:17-22:04.

2. Additionally, Ms. Parrish stated that the contractors were inaccurately describing the procedure at issue as sclerotherapy, but such characterization is not correct, as the procedure at issue was a MOCA procedure that was distinct from sclerotherapy. *Id.* Ms. Parrish argued that the LCD the contractors applied in this case (L32678) was specific to sclerotherapy and did not apply to the MOCA procedure, so this LCD could not be used to justify a denial. *Id.*

3. At the hearing, Dr. O'Donnell described the difference between the MOCA procedure and sclerotherapy. File 12, 30:08-36:24. In MOCA, a catheter is placed in the vein and the catheter turns around inside the vein to open it up; it is a non-thermal embolization method used in areas where there is a risk of nerve injury. *Id.* In sclerotherapy, medication is injected into the vein; it is primarily used for cosmetic purposes. *Id.* Also, sclerotherapy is used on small veins while MOCA is used on larger veins. *Id.* Here, the purpose of the procedure was not cosmetic, and the veins were large. *Id.* While some of the chemical agents used in both procedures can be the same, the goals and methods of each procedure are entirely different. *Id.*

4. Dr. O'Donnell further testified that the FDA approved MOCA a few years before the date of service, but the coding for the procedure had not yet been established on the date of service. *Id.* The manufacturer told her that 50% of other doctors using MOCA were coding the procedure as 37241. *Id.* She testified that Cigna, another private insurer with whom her practice worked, specifically mandated the use of CPT code 37241 for MOCA, and they would not pay her for MOCA under other codes. *Id.* Dr. O'Donnell testified that she read the description of code 37241, and it did appear to be very close, if not identical, to what she was doing while performing a MOCA procedure. *Id.* Dr. O'Donnell said she had been using code 37241 for 1.5 years with success prior to getting audited and having the code overturned. *Id.*

Documentation

5. The date of service at issue here is July 31, 2014. File 2, pgs. 1-5.

6. An abbreviated surgical record dated July 31, 2014, shows the beneficiary had a diagnosis of Varicose Veins, Leg (454.8). File 1, pg. 4. This record also shows that Dr.

O'Donnell performed a procedure identified as a "Left Great Saphenous mechanical occlusion with chemical assistance." *Id.* This record describes the procedure in detail. *Id.*

7. The additional medical records provided include a Letter of Medical Necessity detailing the beneficiary's condition, specifically noting the ultrasound and doppler testing results. File 11, pgs. 4-5. This document demonstrates that the beneficiary has compresses arteries at the right saphenous distal thigh and the left saphenous SFJ. *Id.*

B. Analysis

1. Issue # 1 - Were the physician's surgical services properly billed under code 37214 such that they were covered and payable on the date of service?

The MAC denied the service at issue, citing LCD L32678 and asserting that Dr. O'Donnell should have performed an ablation instead of sclerotherapy based on the size of the vein. File 4, pg. 41. The QIC denied the claims at issue, stating that the record did not contain documentation for the date of service to support a covered diagnosis and to substantiate the actual performance of the billed service. File 2, pg. 3. Appellant argues that she did in fact perform an ablation, so the MAC was factually incorrect. *See* File 12, 15:17-22:04 and 30:08-36:24; File 1, pg. 2. Appellant also argues that medical records were submitted, as confirmed by the MAC decision, in contrast to the QIC denial based on a lack of evidence. *Id.* Further, Appellant asserts that the coding used for the procedure was accurate at the time of the date of service. *Id.*

This record shows that Dr. O'Donnell indeed performed a left great saphenous mechanical occlusion with chemical assistance (MOCA), as opposed to sclerotherapy. File 1, pg. 4. While the surgical record document uses the words "sclerotherapy volume," Dr. O'Donnell's testimony that a sclerotherapy agent can be used in the MOCA procedure accounts for this inclusion. *See* File 12, 30:08-36:24.

Since the medical record and testimony clearly demonstrate that the MOCA procedure was used and not a sclerotherapy procedure, the evidence shows by a preponderance that LCD L32678, as cited by the MAC and as it existed in 2014, does not apply; LCD L32678 does not address the MOCA procedure. Thus, inconsistent with the conclusion of the MAC, LCD L32678 cannot limit coverage in this case.[2]

This leaves the issue of whether code 37241 was an appropriate code under which to bill. Based on the testimony and argument presented at the hearing, this ALJ finds credible that, in 2014, the MOCA procedure was a relatively new FDA-approved procedure for which an LCD had not yet been created and for which a CPT code had not yet been established. This ALJ finds credible that in the absence of an applicable CPT code, Dr. O'Donnell was using guidance from

2 The first instance of MOCA being added to the LCDs did not occur until January 1, 2018, when it was added to LCD L33575.

the manufacturer and a commercial insurer (Cigna) that code 37241 was the closest appropriate CPT code under which to bill the MOCA. Because there was no applicable policy that precluded the use of this code and the standard practice at the time for at least 50% of like surgeons and at least one commercial payer was to use this code, a preponderance of the evidence supports that the service at issue herein was validly coded. This is especially true where CMS did not tell Dr. O'Donnell to use CPT code 37999 until 2016, after the date of service in this case. Accordingly, this decision is favorable to Appellant.

2. Issue # 2- If the services were not covered, do the limitation of liability provisions under Section 1879 of the Act apply? If not, who is financially responsible?

As this decision is fully favorable to Appellant, no limited liability analysis is necessary.

CONCLUSIONS OF LAW

1. Because the general CPT code 37999 had not yet on the date of service been instructed as the default CPT code pending approval of the eventual on-point CPT code for MOCA procedures, the physician's services billed by Appellant under CPT code 37241 for the date of service are covered and payable by Medicare.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE.** The Medicare contractor shall process the claim in accordance with this decision.

SO ORDERED

Andrea R. Barraclough

Andrea Barraclough
Administrative Law Judge

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